REMARKS

I. Restriction and Election of Species Requirements

Claims 20-37 are pending. A restriction requirement under 35 U.S.C. §§121 and 372 was issued in the subject application. It is alleged that the subject application contains the following inventions or groups of inventions which are independent and patentably distinct:

Group I: method claims 20-24 - administration of a P-CAB compound of formula I;

Group II: method claim 20 - administration of a P-CAB compound excluding formula I, i.e., excluding Group I;

Group III: method claims 32-33 - administration of soraprazan;

Group IV: method claim 32 - administration of a reversible ppi other than soraprazan, i.e., excluding Group III;

Group V: pharmaceutical formulation claims 25-31 - comprising a P-CAB compound of formula I;

Group VI: pharmaceutical formulation claims 25-27 - comprising a P-CAB compound excluding formula I, i.e., excluding Group V;

Group VII: pharmaceutical formulation claims 34-37 - comprising soraprazan; and

Group VIII: pharmaceutical formulation claims 25-27 - comprising a reversible ppi other than soraprazan, i.e., excluding Group VII.

In response to the restriction requirement, Applicants elect Group I ***with traverse***. In addition to the restriction requirement, the claims are subject to an election of species requirement. In response to the election of species requirement, Applicants elect ***with traverse*** the second recited compound of claim 23: 2,3-dimethyl-8-(2,6-dimethylbenzylamino)-N-hydroxyethyl-imidazo[1,2-a]pyridine-6-carboxamide as a free base, i.e., neither as a hydrochloride salt or mesylate sale. Claims 20-23 of Group I read on the elected species.

II. Traversal of the Restriction and Election of Species Requirements

Applicants traverse the restriction requirement only with regard to Groups I and II. The remaining Groups III-VIII are withdrawn from consideration in the pending application.

Groups I and II are directed to a new use of a potassium-competitive acid blocker (P-CAB). That new use is the treatment of sleep disturbance due to ***silent*** gastroesophageal reflux ("GERD"). As defined by the specification at page 1, lines 20-28, a patient suffering from silent

GERD does not experience heartburn symptoms or other typical reflux symptoms, e.g., regurgitation. Rather, the target population includes patients having disrupted or fragmented sleep in response to a reflux event which the patient may or may not recall having had. Applicants have surprisingly found that the reflux of acidic contents into the esophagus causes arousals or awakenings even if the reflux episode is not associated with typical GERD symptoms. The patient suffers reduced sleep quality, productivity and quality of life.

In support of the restriction requirement, the Examiner relies on WO 99/55706 and alleges that the P-CAB compounds of formula I are known in the art, e.g., WO 99/55706 (See Office Action at page 4). At page 15, lines 7-27, WO 99/55706 discloses compounds which may be used for the prevention and treatment of gastrointestinal inflammatory diseases and gastric acid-related diseases.

However, by definition, the target patient population of the claimed method does not experience heartburn symptoms or other typical reflux symptoms, e.g., regurgitation. Rather, the principle symptom is sleep disturbance due to a reflux event which the patient may not recall having had. Therefore, the claimed invention is directed to a new use and distinct target patient population relative to the prior art. As such, the special technical feature of Groups I and II, i.e., the administration of a P-CAB for the treatment of silent GERD, defines a contribution over the art. For all of the foregoing reasons, withdrawal of the restriction between Groups I and II is requested.

Applicants traverse that portion of the election of species requirement which requires Applicants to identify the hydrochloride or mesylate salt of the elected species (See Office Action at page 5). A thorough examination of the base compound should encompass salts of the base compound without any additional burden on the Examiner.

CONCLUSION

For all of the foregoing reasons, the Examiner is requested to withdraw the restriction with respect to Groups I and II and withdraw the requirement that the election of species include an identification of the hydrochloride or mesylate salt of the elected species.

The Commissioner is authorized to charge any fee which may be due in connection with this communication to Deposit Account 23-1703.

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Respectfully submitted,

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